THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE GENZYME CORP. SECURITIES LITIGATION	Consolidated No. 09-cv-11267 (GAO)
	Leave to File Granted On June 20, 2012

DEFENDANTS' JOINT REPLY TO LEAD PLAINTIFFS' NOTICE OF SUPPLEMENTAL AUTHORITY IN SUPPORT OF THEIR MOTION FOR RELIEF FROM FINAL JUDGMENT UNDER RULE 59

No motion to dismiss is pending in this case. The defendants' motions to dismiss were granted, judgment has entered and the case is closed. The only pending issue is the plaintiffs' effort to amend the judgment on the ground of "manifest error" in order to seek leave to amend the dismissed pleading. That motion, pursuant to Fed. R. Civ. P. 59(e), insists the Court's dismissal ruling was founded on a *factual* error, thereby warranting the requested relief. As the defendants' response to that motion demonstrated, the plaintiffs' claim to factual error is both wrong and beside the point.

The Eighth Circuit decision that is now the subject of the plaintiffs' *third* Notice of Supplemental Authority, *Pub. Pension Fund Grp. v. KV Pharm. Co.*, No. 10-3402 (8th Cir. June 4, 2012), does not – and self-evidently cannot – have any bearing on the plaintiffs' claim of *factual* error in the Court's ruling. Obviously, nothing the Eighth Circuit did or said reflects on the unique facts of this case.

But more importantly, nothing in *KV Pharmaceutical* could alter this Court's fundamental legal conclusion. The court dismissed the Complaint for its failure "to adequately allege the essential element of *scienter*." Order and Opinion (Docket No. 100) at 22. The new Eighth Circuit ruling barely addresses *scienter*, and otherwise merely repeats the uncontroversial

tenet that allegations of materially false or omitted facts are context-specific, tested "in light of the circumstances under which they are made." *KV Pharm.*, No. 10-3402, at 111. That was precisely the principle this Court, too, applied when it dismissed the plaintiffs' Complaint. *See* Opinion and Order at 14, 18.[1]

With regard to the portion of the Complaint addressing Genzyme's allegedly *deliberate* non-disclosure of the October 2008 Form 483 until March 2009, the Court took account of the alleged circumstances, including the stream of disclosures by the Company during the period, and determined that the plaintiffs had not adequately raised a "strong inference" that defendants acted with an intent to deceive the market. *See* Opinion and Order at 18 (noting that to state a claim "the complaint would have to be far more specific about why the defendants' omissions to disclose [the Form 483] was done with the requisite intent to deceive"). The Court did not dismiss the Complaint on the grounds that none of the alleged misstatements possibly could be *material*; the Court deliberately chose not to reach that question – which the parties also contested – and dismissed the Complaint on scienter grounds alone. The Court's reasoning in dismissing the Complaint was entirely consistent with the Eighth Circuit's holding in *KV Pharmaceutical* that Form 483s "may" render statements about regulatory compliance false or misleading "in some circumstances." *KV Pharm.* at 15.[2] The Court merely concluded that no

[1] The plaintiffs' strain mightily in their Notice of Supplemental Authority to inflate the significance of the Eighth Circuit's decision *KV Pharmaceutical*, characterizing the district court's ruling in that case as a "key decision" relied upon by this Court in its dismissal ruling. Notice of Supplemental Authority, at 1. But this Court's Order and Opinion cited the district court decision precisely *once* – and in support of a purely factual proposition. *See* Order and Opinion at 17-18 ("The language [noting that inspectional observations do not represent final agency determinations regarding compliance] was added to Form 483 by the FDA to minimize any 'perceived ambiguity [that might] result in inaccurate conclusions about the compliance of an inspected firm.' *Pub. Pension Fund Grp. v. KV Pharm. Co.*, 705 F. Supp. 2d 1088, 1100 (E.D. Mo. 2010) (citing FDA website).").

[2] To the extent the Eighth Circuit's ruling can be read to say that Form 483s are presumptively

combination of alleged facts sufficed to raise a compelling inference that Genzyme had acted with an intent to deceive, even with regard to the allegation that Genzyme had delayed disclosure of the October 2008 Form 483.

While the legal principles applied by the Eighth Circuit are perfectly in keeping with those applied by the Court in its dismissal ruling, the alleged *factual* circumstances in the two cases are wildly divergent. The plaintiffs' claim in their Notice of Supplemental Authority that this case "mirror[s]" *KV Pharmaceutical* is fanciful. Pls.' Not. of Supp. Authority 2. First, the alleged misstatements at issue in the two cases are crucially different: while the alleged misstatements in this case go mostly to Genzyme's expectations concerning timely Lumizyme approval, KV Pharmaceutical was alleged to have stated at least ten times in the relevant period that it was or believed it was in compliance with cGMPs. *KV Pharm.* at 3, 11. In the Eighth Circuit's analysis, the fact that the alleged misstatements squarely addressed cGMP compliance was a decisive consideration. *KV Pharm.* at 3, 11 ("[T]he issuance of Form 483s may render a defendant's *statement about its compliance with FDA regulations or cGMP* false, or at least misleading, in some circumstances.") (emphasis added).

Moreover, the alleged circumstances surrounding the Form 483s at issue in the two cases also are starkly different. KV Pharmaceutical allegedly received seven Form 483s over six years, none of which was disclosed during the putative class period in that case.[3] Here, in

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material, this holding clashes with precedent in other courts, including this one. *See, e.g.*, *In re Boston Scientific Corp. Sec. Litig.*, 490 F. Supp. 2d 142, 160-61 & n.113 (noting that even warning letters are, by the terms of their own language, "informal and advisory"), *rev'd on other grounds*, *Miss. Pub. Emps. Ret. Sys. v. Boston Scientific Corp.*, 523 F.3d 75, 86 (1st Cir. 2008); *see also Acito v. IMCRA Grp., Inc.*, 47 F.3d 47, 52-53 (2d Cir. 1995) (noting that "[i]t would be unduly burdensome and impractical to publicly disseminate the results of every inspection of every plant").

[3] *KV Pharmaceutical* also involved allegations of serious intentional misconduct on the part of the defendants, including upper management, by giving instructions to violate Quality

contrast, Genzyme received the October 2008 Form 483 from the FDA just three months after EMEA, the European regulatory agency, had inspected and *approved* the same facility for the manufacture of Lumizyme. Opinion and Order at 8; Mot. to Dismiss (Docket No. 63) at 31. And Genzyme disclosed the receipt of the Form 483 just months into the putative class period. In an effort to sustain the misimpression that the two cases are at all similar, the Notice of Supplemental Authority elides facts this Court found were "clearly establishe[d]" – that Genzyme *disclosed* its Form 483s and other regulatory communications throughout the class period, while the *KV Pharmaceutical* defendants did not. *See* Order and Opinion at 21 ("Much information of the kind the plaintiffs contend was concealed was in fact made public, and promptly so. The record clearly establishes Genzyme's repeated and timely disclosures of those facts material to investors.").

In the end, the Notice of Supplemental Authority represents merely another thinly veiled attempt by the plaintiffs to re-argue the motion to dismiss, and especially the Court's reasoning that the Complaint failed to adequately plead scienter. The attempt is unavailing, first, because the Court's reasoning was entirely correct: citing Genzyme's "considerable disclosure of adverse information" during the class period, and weighing all other allegations (including its response to and eventual disclosure of the October 2008 Form 483), the Court properly credited a more compelling inference that:

> Genzyme was attempting to develop a biologic that the defendants considered to be beneficial and that they believed was progressing, if fitfully at times, towards FDA approval for Lumizyme, and that they reasonably did not expect the setbacks the company experienced in various ways would have a significant impact on the ultimate approval so as to require more disclosure than there had been.

Control/Quality Assurance procedures, *KV Pharm.* at 6, blending production lots resulting in weaker drugs, *id.* at 6-7, and concealing information from the FDA, *id.* at 7.

Opinion and Order at 21 (noting that scienter is lacking because "the inference of a nonculpable explanation for the defendants' actions is stronger than the one the plaintiffs implore the Court to draw"). The Notice is unavailing, too, because it fails to articulate a genuine basis for concluding that the Order and Opinion was the result of an error that justifies any amendment or alteration of the Court's judgment. The decision in *KV Pharmaceutical* neither changes the law in any decisive (or controlling) manner nor bears any relevance to the Complaint here, given the substantial factual differences between the two cases.

CONCLUSION

For the reasons set forth above, Genzyme respectfully requests that the Court deny the plaintiffs' Rule 59(e) motion and uphold the judgment dismissing the complaint in its entirety.

Dated: June 22, 2012

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing on June 22, 2012.

/s/ John D. Donovan, Jr.
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